DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 4, 2014

Wright Medical Technology, Incorporated
% Leslie Fitch, Ph.D.
Senior Regulatory Affairs Specialist
1023 Cherry Road
Memphis, Tennessee 38117

Re: K141746
Trade/Device Name: AS20 Composite Bone Graft
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: June 27, 2014
Received: June 30, 2014

Dear Dr. Fitch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141746

Device Name
AS20 Composite Bone Graft

Indications for Use *(Describe)*
AS20 resultant paste is intended for use as a bone graft substitute to be injected or digitally packed into open bone voids/ gaps that are not intrinsic to the stability of bony structure of the skeletal system (i.e., the extremities and pelvis) to cure in situ. These open bone voids may be the result of benign bone cysts and tumors (in adults and pediatric patients ≥ 6 years old), surgically created osseous defects or osseous defects created from traumatic injury to the bone. The paste provides a bone graft substitute that resorbs and is replaced with bone during the healing process.

The AS20 paste cured in situ provides an open void/gap filler that can augment provisional hardware (e.g. K Wires) to help support bone fragments during the surgical procedure. The cured paste acts only as a temporary support media and is not intended to provide structural support during the healing process.

AS20 is provided sterile for single use only.

The AS20 Core Decompression Procedure Kit, consisting of a bone void filler and manual surgical instruments, is intended to be used during core decompression procedures. The bone void filler component resorbs and is replaced with bone during the healing process. The bone void filler included in the AS20 Core Decompression Procedure Kit is not intended to be used as a load-bearing device.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Laurence D. Coyne -A

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K141746

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the AS20 Composite Bone Graft.

(a)(1). Submitted By: Wright Medical Technology, Inc.
1023 Cherry Road
Memphis, TN 38117

Date: June 27, 2014

Contact Person: Leslie Fitch, PhD
Senior Regulatory Affairs Specialist
Office: (901) 867-4120
Fax: (901) 867-4190

(a)(2). Proprietary Name: AS20 Composite Bone Graft
Common Name: Bone Void Filler

Classification Name and Reference: 21 CFR 888.3045 – Class II

Device Product Code, Device Panel: MQV, Orthopedic

(a)(3). Predicate Devices: K132656: PRODENSE® Bone Graft Substitute

(a)(4). Device Description

AS20 is a bone graft substitute to be injected and/or digitally packed into open bone voids/gaps that are not intrinsic to the structural stability of the skeletal system and cure *in-situ*. It is supplied in a syringe mix package (dual syringes of powder and liquid vial) for mixing it into a paste and delivering it to the defect site. When the components are mixed according to directions, an injectable paste forms and subsequently hardens via hydration reactions. The benefits of this composite include:

- Calcium Sulfate
  - Primary osteoconductive filler
  - Resorbs first primarily through simple dissolution to allow early vascular infiltration
  - Excellent clinical history
- Calcium Phosphate
  - Osteoclastic resorption
  - Secondary porous scaffold that is resorbed after primary filler
  - TCP granules are resorbed in the third and final phase

(a)(5). Intended Use

AS20 resultant paste is intended for use as a bone graft substitute to be injected or digitally packed into open bone voids/gaps that are not intrinsic to the stability of bony structure of the skeletal system (i.e., the extremities and pelvis) to cure *in situ*. These open bone voids may be the result of benign bone cysts and tumors (in adults and pediatric patients ≥ 6 years old), surgically created osseous defects or osseous defects created from traumatic injury to the bone. The paste provides a bone graft substitute that resorbs and is replaced with bone during the healing process.

AS20 paste cured in situ provides an open void/gap filler that can augment provisional hardware (e.g. K Wires) to help support bone fragments during the surgical procedure. The cured paste acts only as a temporary support media and is not intended to provide structural support during the healing process.

AS20 is provided sterile for single use only.

AS20 Core Decompression Procedure Kit

The AS20 Core Decompression Procedure Kit, consisting of a bone void filler and manual surgical instruments, is intended to be used during core decompression procedures. The bone void filler component resorbs and is replaced with bone during the healing process. The bone void filler included in the AS20 Core Decompression Procedure Kit is not intended to be used as a load-bearing device.

(a)(6). Technological Characteristics Comparison

The subject shares many technical characteristics with the predicate PRODENSE® (K132656). The implant material is identical. The only differences are the addition of a smaller volume kit and the addition of syringe mixing accessories for the smaller volume kits (2-10 cc).

(b)(1). Substantial Equivalence – Non-Clinical Evidence

Performance testing shows that the subject device is substantially equivalent to the predicate. Testing of the subject implant mixed with the subject or predicate mixing system included dissolution, porosity, Vicat set time, Gillmore set time, and diametral tensile strength.

(b)(2). Substantial Equivalence – Clinical Evidence

N/A

E2-2

(b)(3). Substantial Equivalence – Conclusions

The design characteristics of the subject system do not raise any new types of questions of safety or effectiveness. From the evidence submitted in this 510(k), the subject device can be expected to perform at least as well as the predicate device.

E2-3